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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/397,957 | 09/17/1999 | Hau H. Duong | A-65686-1 | 9453 |

7590 01/23/2003

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| EXAMINER |
|---|
| LU, FRANK WEI MIN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 01/23/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/397,957 | DUONG ET AL. | |
| | Examiner | Art Unit | |
| | Frank W Lu | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1)☒ Responsive to communication(s) filed on *10/3/2002 and 11/18/2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *11,14, 15, 19, 20, and 28-50* is/are pending in the application.

4a) Of the above claim(s) *15, 20, 31-34, 39, 41, 42, 49, and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 14, 19, 28-30, 35-38, 40, and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election without traverse of species nucleic acid (claim 14), species the use of a peak recognition scheme (claim 19), species ferrocyanide (claim 32), species fitting said harmonic components to a first curve and a second curve (claims 44-48), and species a voltage wave in Paper No. 20 is acknowledged. Claims 11, 14, 19, 28-30, 35-38, 40, and 43-48 will be examined.

### *Sequence Rules Compliance*

2. The sequencing listing filed on July 2, 2002 has complied with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

### *Inventorship*

3. In view of the papers filed on November 18, 2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(c). The inventorship of this application has been changed by adding Gary Olsen, Javier Gonzalez, and Daniel Litvack.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28-30, 35, 40, and 44-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Although the specification describes the limitation in claim 11, the specification does not adequately describe an asymmetrical response in claims 28-30, an even harmonic component in claim 40, and method steps recited in claims 44-48. MPEP 2163.06 states that "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." In view of the embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of the claimed invention at the time of the application was filled. Therefore, the written description requirement has not been satisfied.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description"

requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11, 14, 19, 28-30, 35-38, 40, and 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 11 is rejected as vague and indefinite in view of the phrase "at least one of which comprises an assay complex" because it is unclear what represents "at least one of which" in the step a). Please clarify.

9. Claim 28 is rejected as vague and indefinite in view of the phrase "an asymmetrical response to said input waveform" because it is unclear what kind of response can be considered as an asymmetrical response. Please clarify.

10. Claim 35 is rejected as vague and indefinite because it is unclear what kind of enzyme-coupled reaction causes said asymmetrical response. The phrase "due to" does not indicate how an enzyme-coupled reaction causes said asymmetrical response. Please clarify.

11. Claims 37 and 38 recite more than one harmonic components in the claims. There is insufficient antecedent basis for this limitation in the claims since an output waveform of claim 1 only comprises a harmonic component.

12. Claim 40 is rejected as vague and indefinite because it is unclear what kind of harmonic component can be considered as an even harmonic component. Please clarify.

13. Claim 48 is rejected as vague and indefinite because it is unclear what means "said fitting said fifth order polynomial comprises using singular value decomposition". Since the phrase "using singular value decomposition" means using a method and is not a composition, it is unclear what comprises said fitting or said fifth order polynomial. Note that there is no connection word between "said fitting" and "said fifth order polynomial". Please clarify.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 11, 14, 36, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Kayyem *et al.,* (US Patent No. 6,232,062, filed on August 14, 1997).

Kayyem *et al.,* teach AC methods for the detection of nucleic acid.

Regarding claims 11 and 14, the methods comprised applying a first input signal comprising an AC component and a non-zero DC component to a hybridization complex comprising at least a target sequence and a first probe single stranded nucleic acid. The hybridization complex was covalently attached to a first electron transfer moiety comprising an electrode, and a second electron transfer moiety. The presence of the hybridization complex was detected by receiving an output signal comprising a current characteristic of electron transfer through said hybridization complex (see columns 2 and claims 1-30 in columns 73-76). Since, according to Britannica online (see attachment), motion of electrons in a wire carrying alternating current (AC) was considered as simple harmonic motion, an output signal generated from input signal comprising an AC component was considered to have a harmonic component as recited in claim 11.

Regarding claim 36, Kayyem *et al.*, teach to apply a first input signal comprising an AC component at a first voltage amplitude and a second input signal comprising said AC component at a second voltage amplitude to the hybridization complex in the electronic detection (see column 2). Since the electronic detection was non-linear (see column 43, first paragraph) and the electronic detection was required to detect the output signal, the output signal was considered as non-linear as recited in claim 36.

Regarding claim 43, a plurality of input signals including multiple frequencies were applied in the detection (see column 49, second paragraph).

Therefore, Kayyem *et al.,* teach all limitations recited in claims 11, 14, 36, and 43.

***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 11, 14, and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,232,062.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 11 and 14 in this instant application are not identical to claims 1-30 of US Patent No. 6,232,062 and claims 1-30 of US Patent No. 6,232,062 do not directly disclose an output waveform comprising a harmonic component as recited in claim 11, this limitation is considered to be inherent taught by U.S. Patent No. 6,232,062. Since an input signal in claim 1 of U.S. Patent No. 6,232,062 comprises an AC component and an output signal in claim 8 of U.S. Patent No. 6,232,062 comprises a current, according to the definition of "simple harmonic motion" (see above attachment), the examiner considers that an output signal comprising a current in claim 8 of U.S. Patent No. 6,232,062 is harmonic. Claim 43 in this instant application is similar to claim 13 of US Patent No. 6,232,062. Therefore, claims 1-30 of US Patent No.6,232,062 are directed to the same subject matter and fall entirely within the scope of claims 11, 14, and 43 in this instant application. In other words, claims 11, 14, and 43 in this instant application are anticipated by claims 1-30 of US Patent No. 6,232,062.

***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Meade (US Patent No. 6,013,459) was considered as a prior art to reject at least claims 11, 14, and 36.

19. No claim is allowed.

20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
December 30, 2002

Ethan Whisenant, Ph.D.
Primary Examiner (FSA)